

Notice of Allowability

Application No.

10/718,337

Examiner

Amelia A. Owens

Applicant(s)

BORCHARDT ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response filed 11/30/2005.
2. ☒ The allowed claim(s) is/are 5-32.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 27 line 2 replace [1,5-a- with -----[1,5-a]-----

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

1. Claims 5-32 are pending.
2. The rejection of claims under 35 USC 112, 1st paragraph is dropped. Applicant's remarks are persuasive.

Where the application at issue claims compounds per se and bases the utility of such compounds on a pharmacological activity, the Federal Circuit has clearly delineated the procedure that must be followed in making a rejection under either a 101 or a 112, first paragraph, for lack of utility. See *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995). First, the applicant must have alleged a sufficiently specific use for the compounds. *Id.* at 1555. Here applicant's specific utility is to treat hepatitis C virus (HCV). HCV is known to be treatable by ribavirin. See Crotty, Ribavirin's antiviral mechanism of action: lethal mutagenesis?, *J Mol Med* (2002) 80:86-95 @ 86.

Second, the Examiner then has the burden to challenge this presumptively correct assertion of utility by providing evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility. *Id.* at 1566; see *Ex Parte Rubin*, 5 U.S.P.Q.2d 1461, (BPAI 1987) C. . . a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility

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sufficient to satisfy the utility requirement for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope. (quoting *In re Lancer*, 503 F.2d 1380 (CCPA 1977)). Such evidence must tend to show that the claimed invention relates to an inherently unbelievable undertaking or involves implausible scientific principles. *In re Brana*, 51 F.3d 1560 (emphasis added).

The *in vitro* data at pages 495-513 demonstrates the claimed compounds possess activity as inhibitors of HCV polymerase enzyme.

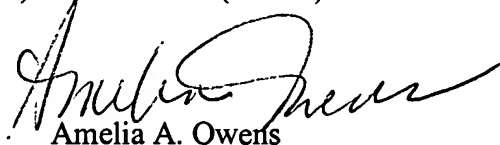
3. Claims 5-32 are allowed. The prior art neither teaches nor suggests the claimed compounds. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal et al*, 158 USPQ 320; *Ex parte Krenzer*, 199 USPQ 227.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens
Primary Examiner
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